SUBMISSION ON THE ACIP INQUIRY INTO

"PATENTING OF BUSINESS SYSTEMS"

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The Australian Centre for Intellectual Property in Agriculture (ACIPA) is a research centre based at the law schools of the Australian National University in Canberra and Griffith University in Brisbane. It commenced operations in September 2000 to undertake research in issues relating to intellectual property law, and apply that knowledge to the scientific community and industry and rural bodies. The Centre's ultimate purpose is to foster an active environment in which Australia better protects and capitalises the products of research and innovation. It has particular expertise in patent law and biotechnology.

ACIPA would like to make a submission in respect to the ACIP inquiry into "Patenting of Business Systems". It will limit its comments to the issues raised by the inquiry in respect of intellectual property and biotechnology. ACIPA suggests that the inquiry needs to pay special attention to the impact of patenting business systems upon the emerging field of bioinformatics. It maintains that bioinformatics should be outside the scope of allowable patent claims. This submission builds upon research undertaken by ACIPA into intellectual property and bioinformatics.[1]

[1] Rimmer, M. "Beyond Blue Gene: Intellectual Property and Bioinformatics", *IIC*, 2002 (forthcoming).

Part 1

Bioinformatics

Bioinformatics is the art and science of using computer systems to store, manage and analyse biological information. It brings together the diverse disciplines of mathematics, statistics, engineering, and computer science to map and model genes and proteins. Bioinformatics played a critical role in mapping the human genome in both the large public and commercial projects. Robert Cook-Deegan notes:

> Databases, computers, and mathematical algorithms proved as important as DNA sequencing, cloning, and other more obviously biological techniques. As geneticists produced a deluge of data during the 1990s and beyond, those who understood hardware and software would play an increasingly important role.[2]

The public consortium relied upon cloning methods to map the location of genes, dividing the genome into small blocks. The private efforts lead by Celera Genomics engaged in whole genome shotgun sequencing, fracturing the DNA of an organism into small fragments and then using powerful computer sequencing machines to identify the base pairs at the end of each

[2] Cook-Deegan, R. *The Gene Wars: Science, Politics, And The Human Genome*. New York and London: WW Norton and Company, 1994, p. 288.

fragments. The sequencing, storage and retrieval of genetic information have generated new possibilities for understanding the function and structure of genes and proteins.

Gene chip or microarray technology has also been vital to the analysis of genetic sequences. Taking its lead from computer technology, this technique has revolutionized genomic research.[3] Kevin Davies comments upon this technology:

> These DNA chips have generated the biggest buzz in molecular biology circles since the advent of the polymerase chain reaction - the technique invented by Kary Mullis that amplifies minute traces of DNA - some fifteen years ago.[4]

Microarrays are vast libraries of short DNA sequences attached to tiny glass or silicon supports and are being used to screen nucleic acid population. This revolution in miniaturization and high throughput screening is analogous to what has occurred in the computer industry over the past decades. Consequently, more data can be obtained more quickly than ever before. Affymetrix is the dominant player in the microarray or genechip technology. The patent position is complex and lawsuits that relate to the patent rights in this technology are already

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[3] Ekins, R. and Chu, F. "Microarrays: Their Origins and Applications", *Trends in Biotechnology* 1999, Vol. 17, p. 217; Sinclair, B. "Everything's Great When It Sits on a Chip?: A Bright Future for DNA Arrays", *The Scientist*, May 24, 1999, at 18; Sutherland, G. "The Human Genome Project", *Australian Journal Of Forensic Sciences*, 2000, Vol. 32, p. 19-24.

[4] Davies, K. *The Sequence: Inside The Race For The Human Genome*. London: Weidenfeld and Nicolson, 2001, p 218-219.

in progress on both sides of the Atlantic.[5] Other companies such as Motorola and Hewlett Packard have entered into the market for microarrays and gene chips.

Bioinformatics also plays an essential role in drug development. High throughput screening involves the use of fully automated robotic technologies to test compounds against a molecular gene target identified by genomic approaches. Combinatorial chemistry is used to generate vast on-line libraries of entirely novel chemical entities. Researchers predict that the time and cost it takes to develop drugs will be significantly reduced by biology-based approaches. It now takes about 12 years and $500 million to bring a drug to market. William Haseltine, the Chief Executive Officer of Human Genome Sciences, declared:

> We think we can reduce this by about six years. By both increasing the success rates and shortening the trial period, we think we can dramatically improve cost efficiency in drug discovery.[6]

The providers of bioinformatics services can aid and assist pharmaceutical companies who are engaged in drug discovery. They can also conceivably move into the business of developing and selling drugs themselves.

Part 2

Bioinformatics Patents

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[5] Gilbert, P and Walter, C. “Patents and the Human Genome Project - New Claims for Old”, *Trends in Biotechnology*, Vol. 19 (2), 2001, p. 49.

[6] Philipkoski, K. "Genome Map Heralds Cheap Drugs", *Wired News*, 13 September 2000.

Biotechnology firms have been applying for patents over databases of genetic information, and other proprietary informatics systems for storing and analysing genomic variation data. They have been seeking patents for computer software and computer hardware related to the life sciences. They have been applying for patents over novel business methods that utilise technologies for providing genomic services to the pharmaceutical and biotechnology industry.

Patent attorneys and lawyers have hailed the decision in *State Street Bank* as opening the way forward for the patenting of bioinformatic inventions.[7] Ernest Buff is perhaps representative in his enthusiasm: "*State Street* and its progeny will likely change the way in which biotechnology and bioinformatics industries do business".[8] However, as Stephen Lesavich comments, such patents were well available before the *State Street Bank*.[9] Most bioinformatic inventions - such as those related to software methods, software systems, data structures, the Internet and other software features - were capable of receiving patent protection with software patents under US patent law long before the *State Street Bank* and *AT & T* cases were decided.

Several studies have considered whether the advice of patent attorneys and lawyers has been acted on by biotechnology and information technology firms.

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[7] Sung, L. and Pelto, D. "Bioinformatics May Get Boost From 'State Street': Software That Can Manipulate Vast Libraries Of Genetic Data May Receive Patent Protection", *The National Law Journal,* Vol. 21 (8), 19 October 1998.

[8] Buff, E. et al "State Street Alters Landscape Of Biotechnology and Bioinformatics", *New Jersey Law Journal*, Vol. 157 (4), 26 July 1999.

[9] Lesavich, S. "Bioinformatic Tools", *The National Law Journal*, 16 October 2000.

Silico Research

A recent study conducted by London-based consulting firm Silico Research found that only 50 software-related patents had been issued by the US Patent and Trade Mark Office between 1996 and 2001 to companies operating in the pharmaceutical, biotechnology, and genomics research.[10] The study covered 317 companies. The firm searched for United States patents assigned under the international classification G06, which covers computers, databases, networks, and computing methods. The study excluded biological, pharmacological and chemical patents. It did not take account of pending patents. It also excluded patents issued to software companies like Microsoft, Oracle and IBM.

The senior partner of Silico Research Emmett Power found unexpected results regarding the number of patents over bioinformatics products:

> We were genuinely surprised by the lack of technology and method patents issued to pharmaceutical and biotechnology companies. We had expected large pharmaceutical companies to be registering significant numbers of technology and method patents as a matter of course.
>
> After all, they employ teams of computer scientists in original research roles and they are highly patent-focused as part of their business and value creation methodology. Add the fact that senior executives throughout the industry are preaching the importance of the convergence of life and information technologies and we had expected to see 'convergence patents' staked out across the landscape.

[10] Power, E. "Pharmaceutical Companies Are 'Failing To Patent New Technologies', Silico Research, London, 2 May 2001.

> However, it appears that large pharmaceutical companies' intellectual property efforts are still exclusively focused on compounds and genes as research and development end-points. In the process, they are ignoring the value of any original methods and computer technology developed to get to those end-points.[11]

The study concluded that the leading patent issuers in the sector were Incyte and Affymetrix with six patents each. They were followed by PE corporation with five patents, and Tripos, 3-Dimensional Pharmaceuticals, and Entelos each had three patents. A number of companies had registered one patent.

Nature Biotechnology Study

Another study published by *Nature Biotechnology* provides a sharper image of the changing marketplace of bioinformatics.[12] Paolo Saviotti and his collaborators sought to assess the commercial activity in bioinformatics by searching the Derwent Biotechnology Abstracts (DBA) for patents containing the words "computer, computing, DNA chip, biochip, gene chip, bioinformatics or informatics".

Saviotti and his collaborators found that the number of bioinformatics related patents has been increasing steadily from 1979 to 1997 after which there was a notable boom in patent applications, with a peak of sixty patents in 1998.

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[11] *Ibid.*

[12] Saviotti, P., de Looze M-A, Michelland, S., and Catherine, D. "The Changing Marketplace Of Bioinformatics", *Nature Biotechnology*, 2000, Vol. 18 (12), p 1247.

The first group of patentees were companies and institutions interested in applying information technology to production processes. The patents filed were much older (1983-1992). The applicants were commonly Japanese or Russian.

The second group of patentees were pharmaceutical companies, bioinformatics startups and public research institutes interested in applying information technology to research and development processes. Examples include Affymetrix, Affymax and Human Genome Sciences. The date of patents issued to these companies range between 1994 and 2000.

The third group of patentees were companies and instrumentation firms interested in creating tools and solutions for research and development processes. The companies include firms such as Motorola and Kodak which have been involved in mainstream electronics, IT and telecommunications. The patents issued to these companies range from 1992 to 2000.

United States Patent and Trade Mark Office

Such developments will have implications for patent applications and patent examination. The United States Patent and Trade Mark Office reports that the actual number of pending bioinformatics patents is relatively small.[13] Anticipating a rush of patent applications in this emerging area, the organisation had the foresight set up a dedicated bioinformatics art unit in December 1999, which operates under the biotechnology centre. Jasemine Chambers, the director of biotechnology at the United States Patent and Trade Mark Office remarked: "We were a little surprised that we haven't seen the flood of applications that some people have

[13] Toner, B. "Bioinformatics Patents Remain A Rarity In IP-Heavy Biopharmaceutical Industry", *Genomeweb.com*, 4 July 2001.

predicted".[14] Currently the 11 examiners in the bioinformatics art unit are processing a total of around 200 patents. Of those, 160 are in various stages of prosecution and 40 are waiting to be examined. Only 11 have issued from the unit so far. With a turnaround goal of 36 months, Chambers expects a few more bioinformatics patents to issue over the next year.

Future Trends

Recently, a number of mainstream information technology companies - such as IBM, Microsoft, and Compaq - have invested in bioinformatics. Commentators wonder what effect the entrance of these new players might have on the market for bioinformatics:

> The movement of these IT-based entrants into the market is important because they are very large and powerful firms capable of shaking up the industrial structure of bioinformatics. It is tempting to speculate that the expertise of these companies in other industries might be rapidly translated to software solutions that provide the kind of standardization, integration, and analysis of the data so sorely needed.[15]

Furthermore, the information technology firms will have an important impact upon the field of bioinformatics. Such companies have shown great talent in fully exploiting both copyright law and patent law in managing the protection of computer software and hardware.[16] They may be able to translate such tactics and strategies in the management of intellectual property to the field of bioinformatics. The entry of information technology companies into the marketplace may result in a greater activity in patenting. Thus the precedents in relation to Internet business

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[14] *Ibid.*

[15] Saviotti, P., de Looze M-A, Michelland, S., and Catherine, D. "The Changing Marketplace Of Bioinformatics", *Nature Biotechnology*, 2000, Vol. 18 (12), p 1247.

[16] Likhovski, M., Spence, M. and Molineaux, M. "The First Mover Monopoly: A Study On Patenting Business Methods in Europe", *Oxford Electronic Journal Of Intellectual Property Rights*, November 2000.

methods patents have greater relevance to biotechnological inventions than has been previously been thought. They will have an important bearing upon whether bioinformatics - such as databases, computer software, and websites - can be patented.

Part 3

Policy Options

Patentable Subject Matter

First of all, ACIPA argues that special consideration should be given to the situation of bioinformatics. Rebecca Eisenberg makes a strong case that bioinformatics might not be an appropriate subject matter for a patent claim.

> I believe that patent claims to DNA sequences stored in computer-readable medium represent a fundamental departure from the traditional patent bargain of exclusionary rights to tangible inventions in exchange for free disclosure of information and should not be allowed. And I begin from the premise that computer-readable medium is the only practical way to perceive and analyze large volumes of DNA sequence information, even something as relatively simple as the genome of haemophilus influenza…The claim to the sequence in computer-readable medium, in effect, gives the patent holder the right to restrict the ability of others to use the information in a computer-readable medium and thus precludes others from perceiving and analyzing the sequence information itself.[17]

[17] Eisenberg, R. "Molecules v Information: Should Patents Protect Both?", *Boston University Journal of Science and Technology Law*, 2002, Vol. 8, p. 190.

Eisenberg stresses the differences between DNA sequence information and Internet business methods: “Of course DNA sequence information stored is not the same thing as a computer-implemented business method, and it is certainly possible to define boundaries for the patent system that include the latter but not the former”.[18] Two possible options are available in light of this conclusion - one radical; the other a reform. The first radical solution is that bioinformatics should be excluded from a manner of manufacture. The second response is to ensure that the standards of novelty and an inventive step are applied strictly in this field.

Experimental Use and Fair Dealing

Second, Rebecca Eisenberg comments that patent law is an inappropriate regime for the protection of data:

> Patents are the wrong form for that protection to take. They are a very dangerous form of intellectual property rights for information because there are so few safety valves built in to the patent system that constrain the rights of patent holders relative to other models that are out there. For example, unlike copyright law, patent law has no fair use defense. Maureen O'Rourke is here somewhere and has suggested that maybe it should but does not. Patent law has no real research exemption. Patent law has no defense for reverse engineering or for independent creation. Dennis Karjala was saying earlier that none of the proposals for database protection would preclude independent creation. Well, the patent would preclude independent creation of the same information.[19]

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[18] Eisenberg, R. “Re-examining the Role of Patents in Appropriating the Value of DNA Sequences”, *Emory Law Journal*, 2000, Vol. 49, p. 793.

[19] Eisenberg, R. "Molecules v Information: Should Patents Protect Both?", *Boston University Journal of Science and Technology Law*, 2002, Vol. 8, p. 190.

In the United States, Michigan Democrat Congresswoman, Lynn Rivers, has introduced legislation into the House of Representatives of the Congress aimed at preserving research innovation in genetics.[20] Her proposal picks up on academic plans for reform. Donna Gitter argues: "Congress also should codify an experimental-use exemption for public-sector researchers at the federal level and non-profit researchers".[21] Similarly, Maureen O'Rourke argues that patent law needs a defence in respect of research and experimental use, along the lines of the defence of fair use in copyright law.[22] The Australian Government should seriously consider implementing similar reforms to those proposed by Democrats Congresswoman Lynn Rivers. Arguably, the scope of the experimental use exception should be broadly defined to encourage experimental testing and follow-on innovation. Such an exception would dispel the threat of litigation to researchers working in the field of bioinformatics.

Compulsory Licensing

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[20] *The Genomic Research And Diagnostic Accessibility Act* 2002 (US) HR 3697 and *The Genomic Science And Technology Innovation Act* 2002 (US) HR 3966.

[21] D. Gitter, "International Conflicts Over Patenting Human DNA Sequences In The United States And The European Union: An Argument For Compulsory Licensing And A Fair Use Exemption" (2001) 76 *New York University Law Review*, 1623. See also R. Eisenberg, "Patents And The Progress Of Science" (1989) 56 *University Of Chicago Law Review*, 1017; D. Gilat, *Experimental Use And Patents* (1995); and E. Barash, "Experimental Uses, Patents And Scientific Progress" (1997) 91 *North-Western University Law Review*, 667.

[22] M. O'Rourke, "Toward a Doctrine of Fair Use In Patent Law" (2000) 100(5) *Columbia Law Review*, 1177.

Third, there are concerns that monopolistic actors will take charge as the bioinformatic community struggles towards an acceptable degree of standardisation on hardware and software.[23] Brown and others comment:

> Small software developers, once characteristic of the bioinformatics sector, now tend to sell their products to much larger companies. The fear is that the area may become increasingly dominated by a small number of commercial actors providing highly integrated visualisation, search and design packages. Indeed, the dominance of the administrative sector by Microsoft is seen as one paradigm for the way in which computerised biological research will be increasingly served by monopolistic suppliers.[24]

Compulsory licensing could also be applied in the context of Australia.[25] There are admittedly problems in the judicial application of compulsory licensing, and the proper calculation of a reasonable royalty rate. It has been said that such provisions are "cumbersome and expensive to apply".[26] The Intellectual Property Competition Review advocated the reform of the compulsory licensing provisions. It recommended that s. 135 of the *Patents Act* 1990 (Cth) be repealed and that s. 133(2) be amended to include an order requiring a compulsory license to

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[23] Brown, N., Nelis, A., Rappert, B. and Webster, A. "Bioinformatics: A Technology Assessment Of Recent Developments In Bioinformatics And Related Areas Of research And Development Including High-throughput Screening and Combinational Chemistry", Final Report for the Science and Technological Options Assessment Unit, European Parliament, 1999, p 24-25.

[24] *Ibid*, p 25.

[25] Lawson, C. "Patenting Genes And Gene Sequences", *Federal Law Review*, 2002, Vol. 30, p. 97.

[26] Justice Finkelstein in *Bristol-Myers Squibb* v *FF Faulding Co & Ltd* (2000) 46 IPR 553.

be subject to a competition test.[27] The Federal Government responded cautiously that the existing tests should be retained and a competition test be added as an additional ground on which a compulsory licence can be obtained. However sweeping reforms are needed to ensure that compulsory licensing can be deployed in the field of biotechnology.

Patent Administration

The developments in relation to business methods have been a spur for a reform of patent administration. Most notably, Merges was prompted to consider a number of initiatives to improve the operation of the patent office.[28] However, bioinformatics has quite unique and important implications in respect of patent administration, and the examination of prior art. Vondran and Florence comment:

> Bioinformatics inventions are unique, however, because they combine the use of a computer and/or software with biological information. It is crucial, therefore, for patent practitioners to fully understand the case law relating to computers and software as well as biotechnology. Certain aspects of the statutory requirements for patentability are also affected by blending these disciplines. Determining the identity of the person of ordinary skill in the art can be particularly difficult due to the multidisciplinary nature of the field and its rapid rate of change. As bioinformatics evolves, patent practitioners must be willing to

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[27] Intellectual Property Competition Review Committee, *Review Of Intellectual Property Legislation Under The Competition Principles Agreement* (Canberra: Attorney-General's Department, 2000)

[28] Merges, R. "As Many As Six Impossible Patents Before Breakfast: Property Rights For Business Concepts And Patent System Reform", *Berkeley Technology Law Journal Spring,* 1999, Vol. 14 (2), p 577, http://www.law.berkeley.edu/institutes/bclt/pubs/merges/

> adapt if they want to meet the needs of a bioinformatics client. Such willingness must include stretching beyond one's initial training or background to be effective.[29]

Therefore there will be a need for IP Australia to develop a cadre of examiners who can deal with the combination of information technology and biotechnology. Consideration should be given to the development of a special unit to deal with bioinformatics along the lines of the United States Patent and Trade Mark Office. Alternatively, there should be greater collaboration between examiners from the sections dealing with information technology and biotechnology.

Conclusion

ACIPA suggests that the ACIP inquiry into the patenting of business systems should take into special consideration the field of bioinformatics. This cross-over between information technology and biotechnology is important to a number of emerging areas of research - including genomics, proteomics, pharmacogenomics, and biodiscovery. ACIPA points out that the developments in relation to the patenting of computing programs and business methods have important implications for bioinformatics. It identifies a number of studies, which suggest that there is a slow but steady take up of patents in relation to this emerging field. ACIPA queries whether bioinformatics should be treated like other subject matter under patent law. At best, the field should be excluded from the definition of manner of manufacture; at the very

[29] Vondran, C. and Florence, R. "Bioinformatics: Patenting The Bridge Between Information Technology And The Life Sciences", *The Journal Of Law And Technology*, 2002, Vol. 42, p. 93.

least, there is a need for a strict application of novelty and inventive step. There is a need for more expansive defences under patent law - such as experimental use and compulsory licensing. Furthermore there is a need for the patent administration to be properly prepared in the examination in the field of bioinformatics.